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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/583,848 | 05/31/2000 | Beatrice Gaugler | LUD 5353.7 DIV (10016357) | 4358 |

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EXAMINER

DAVIS, MINH TAM B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED: 07/30/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/583,848

Applicant(s)

GAUGLER ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 55-56, 63-64, 66-74.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): Rejection under 35 USC 112, first paragraph, new matter, and Rejection under 35 USC 112, first paragraph, written description.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 54, 57-62 and 65, and adds new claims 68-74 which are related to claims 55, 56, 63-64, 66-67.

Accordingly, claims 55, 56, 63-64, 66-74 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 55, 56, 63-64, 66-74 pertaining to lack of enablement for a nucleic acid molecule that "encodes" a fragment of a tumor rejection antigen precursor or a tumor rejection antigen remains for reasons already of record in paper No.13.

Applicant argues that "fragment" refers to a nucleic acid molecule smaller than a full length tumor rejection precursor, "but larger than a nucleic acid molecule that encodes a tumor rejection antigen" (specification page 44, lines 30-35).

Applicant refers to the 5,405,940 patent, arguing the nucleotides 70-96 of SEQ ID NO:18 in the present application is identical to SEQ ID NO:18 of the '940 patent. Applicant asserts that since SEQ ID NO:18 of the present case is clearly larger than the amino acid sequences needed to encode a tumor rejection antigen, it is a fragment as defined in the claims.

Applicant's arguments set forth in paper No.17 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that page 44, lines 30-35 in the specification of the instant application only discloses that "fragment" refers to a nucleic acid molecule smaller than a full length tumor rejection precursor. There is no limitation that a fragment is "larger than a nucleic acid molecule that encodes a tumor rejection antigen".

It is further noted that the 940' patent discloses that SEQ ID NO:1 of MAGE-1 comprising 9 amino acids could induce specific CTL lysis, and that the first and ninth amino acids of SEQ ID NO:1 is critical for binding and effecting lysis (Example 2, on column 5 and figure 2 of the '940 patent). The 940' patent further discloses that SEQ ID NO:6 (9 amino acids), encoded by SEQ ID NO:18 of MAGE-6 is homologous to SEQ ID NO:1, and different by three amino acids at positions 2, 5 and 8.

There is no disclosure in the '940 patent that SEQ ID NO:6 of MAGE-6 could induce specific CTLs lysis.

One cannot extrapolate the teaching in the 940' patent to the claims, because although the first and ninth amino acids of SEQ ID NO:1 of MAGE-1 is critical for binding and effecting lysis, it has not been shown that the presence of the first and ninth amino acids of SEQ ID NO:1 in any other sequence by itself is sufficient for binding to a MHC molecule, presentation of the antigen, and inducing specific CTLs. It is noted that only a minority of peptide fragments from a protein antigen are able to bind to a particular MHC molecule, and that for presentation of antigen, the antigen has to specifically bind and fit into a particular groove of the MHC molecule (Roitt, I et al, 1998,

Art Unit: 1642

Immunology, 4th ed, Mosby, London, pages 7. 9-7.10), and it is unpredictable that three amino acids at positions 2, 5 and 8 of SEQ ID NO:1 could be replaced with the corresponding amino acids of SEQ ID NO:9 of MAGE-6 without affecting the binding, presentation of SEQ ID NO:1, and inducing specific CTLs.

REJECTION UNDER 35 USC 102(b)

Rejection under 35 USC 102(b) of claim 55 pertaining to anticipation by Kudo et al remains for reasons already of record in paper No.13.

Applicant argues that “fragment” refers to a nucleic acid molecule smaller than a full length tumor rejection precursor, “but larger than a nucleic acid molecule that encodes a tumor rejection antigen” (specification page 44, lines 30-35). Applicant further argues that the cited reference describes a 10 mer oligonucleotide, which is clearly too small to be a “a fragment” as defined by the specification.

Applicant’s arguments set forth in paper No.17 have been considered but are not deemed to be persuasive for the following reasons:

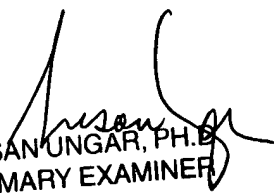
It is noted that page 44, lines 30-35 in the specification of the instant application only discloses that “fragment” refers to a nucleic acid molecule smaller than a full length tumor rejection precursor. There is no limitation that a fragment is “larger than a nucleic acid molecule that encodes a tumor rejection antigen”.

Art Unit: 1642

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

July 24, 2003